EXHIBIT 4

FOOD AND DRUG ADMINISTRATION

IN COLLABORATION WITH THE NATIONAL CANCER INSTITUTE

Methodological Considerations in Evaluation of Cancer as an Adverse Outcome Associated with Use of Non-Oncological Drugs and Biological Products in the Post-Approval Setting

Thursday, September 11, 2014

8:02 a.m. to 3:56 p.m.

Double Tree by Hilton Hotel

The Pinnacle Grand Ballroom

8727 Colesville Road

Silver Spring, Maryland

Meeting Roster

PANEL MEMBERS

Elizabeth B. Andrews, PhD, MPH, BA

Vice President

Pharmacoepidemiology and Risk Management

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Montreal, Quebec, Canada

Laurie Habel, PhD, MPH

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Section Chief, Cancer Research

Kaiser Permanente, Division of Research

Oakland, California

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CDER, FDA

C O N T E N T S

C O N T E N T S (continued)

DR. GRAHAM: Just to sort of address your question, Howard, the work that we're doing with pancreatic cancer, we're using -- it's within our SIMS database, so we're using the SEER diagnosed cases. So there, they have been classified by SEER as pancreatic cancer. So those are the cases that we're using in our diabetes work.

We have developed an algorithm for pancreatic cancer that has very good performance, and our next step will be, when we've completed the study in SIMS -- which actually we're going to be looking at the very first analyses next Tuesday.

When we finish that, we'll then take the algorithm, apply it to the entire Medicare database to test our principle of developing an algorithm in the SEER-Medicare environment, applying it to the entire Medicare environment, getting some of those medical records, and seeing if the results we get in the entire population are the same as the results we got in SEER, that we'll get in SEER and this assay sensitivity.

Then if that works, then the third step will

be to tackle drugs, and the incretins are at the top of our list there. There is a lot of concern about that within the agency, the incretins in pancreatic cancer.

DR. WONG: The public speaker?

DR. HECKMAN-STODDARD: Brandy Heckman-Stoddard, NCI.

Dr. Graham, I also wanted to have you comment on the algorithms in terms of when they were developed in the past years in terms of time and what type of data was used to develop the algorithm, because as statins have increased in usage and the types of treatment for diabetes have changed over time, the risk of microvascular complications may change. So those algorithms might have been developed on earlier data that may not be relevant to today's treatment of diabetes.

DR. GRAHAM: Right. The data that we used for the algorithms covered the period from 2005 to 2009. So we used SEER data from 2005 to 2009 to develop the algorithms.

When we get the data for 2010 and '11 and do